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| 10/624,138 | 07/21/2003 | Edward R. Rensimer | RENS:005-3 | 5551 |

7590 03/09/2007
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| EXAMINER |
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RANGREJ, SHEETAL

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| ART UNIT | PAPER NUMBER |
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3626

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/09/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/624,138

Applicant(s)

RENSIMER ET AL.

Examiner

Sheetal R. Rangrej

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/21/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Prosecution History Summary

- Claims 1-18 are pending.

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant claims the benefit of application 07/877,868 filed on May 4, 1992.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-18 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-18 of prior U.S. Patent No. 5,845,853. This is a double patenting rejection.

4. Claims 1-18 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-18 of prior U.S. Patent No. 6,154,726. This is a double patenting rejection.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-18 are provisionally rejected on the ground of nonstatutory double patenting over claims 40-57 of copending Application No. 09/570,828. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a method, executed by a device operated by a medical staff member, of generating a signal quantifying a physician intervention status of a patient, said signal referred to as a clinical status code.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "205" and "235" have both been used to designate "does patient have diagnosis code?". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is directed to a method of generating a code. There is no specific recitation in the claim of using the code. Thus, it is not seen how a practical application is provided. The method of claim 1 is recited as being executed by a "device" generally disclosed as a hand-held personal computer. Further, the specification insists, "the present invention is not limited to these specific computing hardware types." However, the claimed method does not include post-computer process activity involving independent physical acts outside the computer. Further, the claimed method does not include pre-computer process activity involving the measurement of physical objects or activities as the method calls for the entry of selections. The result of the claimed method is merely the production of a code. As a result, no practical application of the code is found, and it is not applied. Claim 1, therefore, is directed to non-statutory subject matter as it merely manipulates input data according to an algorithm to generate a code.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Dorne (U.S. Patent 5,325,293).

11. As per claim 1, Dorne teaches a method, executed by a device operated by a medical staff member, of generating a signal quantifying a physician intervention status of a patient, said signal referred to as a clinical status code (**Dorne: col 3, lines 20-25; i.e. CPT code**)

said clinical status code being a function of (i) a level of medical history of said patient (**Dorne: FIG. 5E; col 7, lines 54-58**), a level of physical examination of said patient (**Dorne: FIG. 6B**), and a medical decision-making process of said physician treating said patient (**Dorne: FIG. 3D; col 6, lines 44-51**), referred to as key elements of said clinical status code, (ii) a time influence factor (**Dorne: FIG. 6B**) determined as a function of (1) an amount of unit floor time or face-to-face time spent by said physician in connection with an encounter with said patient (**Dorne: FIGS 6A and 6B; i.e. office visit**), or (2) an amount of time spent by said physician in counseling or coordination of care for said patient (**Dorne: FIGS 6A and 6B; i.e. consultation**).

said method comprising the steps of:

- (a) prompting the staff member to select a service type, referred to as a selected service type (**Dorne: FIG. 3A**);

- (b) displaying to said staff member a series of questions, said series of questions being determined by said selected service type (**Dorne: FIG. 3B**);
- (c) prompting the staff member to select, for each respective key element of said clinical status code, one of a plurality of allowable levels for said respective key element, referred to as a selected level (**Dorne: FIGS 5E, 6B, 3D**);
- (d) if said selected service type is associated with a time influence factor, then prompting the staff member to enter an amount of service time (**Dorne: FIG. 6B**);
- (e) if the selected service type does not fall within an exception category, then determining said clinical status code as a function of one or more of (i) said selected service type (**Dorne: FIG. 3A**), (ii) said selected levels (**Dorne: FIGS 5E, 6B, 3D**), and (iii) if the staff member entered an amount of service time, said amount of service time (**Dorne: FIG. 6B**).

12. As per claim 2, the method of claim 1 is as described. Dorne further teaches further comprising the steps of

- (f) prompting the staff member to select at least one of a plurality of diagnoses that are applicable to said patient, each referred to as a selected diagnosis (**Dorne: FIG. 7**), and
- (g) generating a signal corresponding to said selected diagnosis, referred to as a diagnosis code (**Dorne: FIG. 7**).

13. Claims 3-16 are addressed to specific service types that can be performed by a physician. These procedure types are all known medical procedures, and would be addressed by the CPT standard coding system described in **Dorne col 1, lines 14-30**. The Dorne system is capable of generating any CPT codes, and thus is capable of generating CPT codes for any known medical procedure described in the CPT standards.
14. As per claim 17, the method of claim 1 is as described. Dorne further teaches further comprising the step (f) of determining whether the respective selected levels meet a specified set of key-component criteria and if not, assigning a default code as said clinical status code (**Dorne: FIGS 9B-9E**).
15. For claim 18, see remarks for claim 1.

Contact

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheetal R. Rangrej whose telephone number is 571-270-1368. The examiner can normally be reached on Monday-Thursday 8 a.m. to 5 p.m. and every other Friday 8 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRR

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2/22/07

Carolyn Bleck
Patent Examiner - 3626
3/2/07